

What is Claimed:

1 1. An introducer, having a retrograde portion and an anterograde portion,
2 for deployment of an endoluminal device in a distal location from a proximal location, the
3 introducer comprising:

4 a shaft having a distal tip;

5 an inner sheath mounted concentrically over the shaft, wherein the
6 endoluminal device is mounted concentrically over the inner sheath; and

7 an anterograde sheath attached proximally to the distal tip, mounted over the
8 endoluminal device in the anterograde portion of the introducer, and axially moveable
9 relative to the inner sheath by moving the shaft.

1 2. The introducer of claim 1 further comprising anchoring means in at
2 least one of the retrograde portion or the anterograde portion for anchoring the endoluminal
3 device during deployment of the device from its proximal end to its distal end.

1 3. The introducer of claim 2, wherein the anchoring means comprises an
2 inflatable balloon at or near a proximal end of the device.

1 4. The introducer of claim 3, wherein the inner sheath defines a lumen
2 connected to an inner region of the inflatable balloon for communication of a fluid to the
3 balloon for inflation of the balloon.

1 5. The introducer of claim 3, wherein the inflatable balloon is mounted
2 concentrically underneath a retrograde portion of the endoluminal device.

1 6. The introducer of claim 5 further comprising a proximally retractable
2 retrograde sheath mounted concentrically over the shaft and inner sheath in the retrograde
3 portion of the introducer and extending distally over the balloon and a retrograde portion of
4 the endoluminal device.

1 7. The introducer of claim 6 further comprising a medial sheath mounted
2 concentrically between the inner sheath and the retrograde sheath in the retrograde portion of
3 the introducer.

1 8. The introducer of claim 7, wherein the medial sheath has a distal end
2 that terminates proximal of the balloon.

1 9. The introducer of claim 5, wherein the anterograde sheath extends
2 proximally over the balloon and a retrograde portion of the endoluminal device.

1 10. The introducer of claim 1 further comprising a radial spacer for
2 providing sufficient space between the inner sheath and the anterograde sheath to contain the
3 endoluminal device.

1 11. The introducer of claim 10, wherein the radial spacer is attached
2 proximally to the distal tip.

1 12. The introducer of claim 2, wherein the anchoring means comprises a
2 holder in the anterograde portion.

1 13. The introducer of claim 12, wherein the holder is concentrically
2 mounted to the inner sheath and adapted to prevent distal movement of the endoluminal
3 device during distal advancement of the anterograde shaft.

1 14. The introducer of claim 13, wherein the endoluminal device has a
2 length and the holder has a length that is less than the endoluminal device length.

1 15. The introducer of claim 12, wherein the anterograde sheath extends
2 over an entire length of the endoluminal device.

1 16. The introducer of claim 1, wherein the anterograde sheath extends over
2 an entire length of the endoluminal device.

1 17. The introducer of claim 2 further comprising:
2 a proximally retractable retrograde sheath mounted concentrically over the
3 shaft and inner sheath and extending axially over a retrograde portion of the endoluminal
4 device; and

5 a medial sheath mounted concentrically between the inner sheath and the
6 retrograde sheath in the retrograde portion of the introducer and terminating proximally of a
7 proximal end of the endoluminal device.

1 18. The introducer of claim 17, wherein the anchoring means comprises a
2 proximally extended portion of the endoluminal device and a notch in the medial sheath for
3 confining the extended portion between the retrograde sheath and the medial sheath with the
4 retrograde sheath in a first position and for releasing the extended portion with the retrograde
5 sheath in a second, retracted position relative to the medial sheath.

1 19. The introducer of claim 2 further comprising a proximally retractable
2 retrograde sheath mounted concentrically over the shaft and inner sheath and wherein the
3 anchoring means comprises a proximally extended portion of the endoluminal device and a
4 notch in one or both of the inner sheath and the retrograde sheath for confining the extended
5 portion between the retrograde sheath and the inner sheath with the retrograde sheath in a
6 first position and for releasing the extended portion with the retrograde sheath in a second,
7 retracted position relative to the inner sheath.

1 20. The introducer of claim 2 further comprising:

2 a proximally retractable retrograde sheath mounted concentrically over the
3 shaft and inner sheath; and

4 a medial sheath mounted concentrically between the inner sheath and the
5 retrograde sheath in the retrograde portion of the introducer and terminating proximally of a
6 proximal end of the endoluminal device;

7 wherein the anchoring means comprises a proximally extended portion of the endoluminal
8 device and a notch in one or both of the medial sheath and the retrograde sheath for
9 confining the extended portion between the retrograde sheath and the medial sheath with the
10 retrograde sheath in a first position and for releasing the extended portion with the retrograde
11 sheath in a second, retracted position relative to the medial sheath.

1 21. The introducer of claim 2, wherein the anchoring means comprises a
2 tether attached to a proximal end of the endoluminal device.

1 22. The introducer of claim 21 further comprising a proximally retractable
2 retrograde sheath mounted concentrically over the shaft and inner sheath and wherein the
3 tether is attached to a portion of the inner sheath.

1 23. The introducer of claim 22, wherein the tether extends proximally from
2 the device a sufficient distance to terminate outside a body lumen through which the
3 introducer is adapted to be introduced.

1 24. The introducer of claim 22, wherein a proximal end of the tether is
2 attached to means for applying an electrical current or a torsional or tensional force.

1 25. The introducer of claim 21 further comprising:
2 a proximally retractable retrograde sheath mounted concentrically over the
3 shaft and inner sheath and extending axially over a proximal end of the endoluminal device;
4 and

5 a medial sheath mounted concentrically between the inner sheath and the
6 retrograde sheath in the retrograde portion of the introducer and terminating proximally of
7 the endoluminal device proximal end.

1 26. The introducer of claim 25, wherein the tether is attached to one of the
2 medial sheath, the retrograde sheath, or the inner sheath.

1 27. The introducer of claim 26, wherein the tether extends proximally from
2 the device a sufficient distance to terminate outside a body lumen through which the
3 introducer is adapted to be introduced.

1 28. The introducer of claim 27, wherein the medial sheath comprises a
2 lateral channel through which the tether extends.

1 29. The introducer of claim 21, wherein the anterograde sheath extends
2 over an entire length of the endoluminal device.

1 30. The introducer of claim 1 further comprising a proximally retractable
2 retrograde sheath mounted concentrically over the shaft and inner sheath and extending
3 axially over a proximal end of the endoluminal device.

1 31. The introducer of claim 30, wherein the anterograde portion extends
2 over a greater length of the endoluminal device than the retrograde portion.

10081641-026002

1 32. The introducer of claim 30, wherein the retrograde sheath and the
2 anterograde sheath are laterally spaced from one another or abut one another.

1 33. The introducer of claim 30, wherein the retrograde sheath and the
2 anterograde sheath laterally overlap one another.

1 34. A method for deployment of an endoluminal device in a distal location
2 in a body lumen from a proximal location, the method comprising the steps of:

3 (a) inserting an introducer into the body lumen, the introducer comprising
4 a retrograde portion; an anterograde portion; a shaft having a distal tip; an inner sheath
5 mounted concentrically over the shaft with the endoluminal device mounted concentrically
6 over the inner sheath; and an anterograde sheath proximally attached to the shaft distal tip,
7 mounted over the endoluminal device in the anterograde portion of the introducer, and
8 axially moveable relative to the inner sheath;

9 (b) aligning the introducer in a deployment location;

10 (c) extending the shaft to distally advance the anterograde sheath to deploy
11 at least a proximal portion of the endoluminal device; and

12 (d) removing the introducer from the body lumen.

1 35. The method of claim 34, wherein the introducer further comprises
2 anchoring means in the anterograde portion for anchoring the endoluminal device during
3 deployment of the device from a proximal end to a distal end of the device, the method
4 comprising aligning the proximal end of the device with the deployment location in step (b)
5 and confining the endoluminal device between the anchoring means and the advancing
6 anterograde sheath in step (c).

1 36. The method of claim 34, wherein the introducer further comprises
2 anchoring means in the retrograde portion for anchoring the endoluminal device during
3 deployment of the device from a proximal end to a distal end of the device, the method
4 comprising aligning the proximal end of the device with the deployment location in step (b),
5 anchoring the proximal end during step (c), and releasing proximal end prior to or
6 concurrently with step (d).

1 37. The method of claim 36 wherein the anchoring means comprises an
2 inflatable balloon, and the method further comprises inflating the balloon prior to step (c) and
3 deflating the balloon after step (c).

1 38. The method of claim 37 further comprising a proximally retractable
2 retrograde sheath mounted concentrically over the shaft and inner sheath and extending
3 axially over the proximal end of the endoluminal device and the balloon, the method further
4 comprising retracting the retrograde sheath prior to inflating the balloon, and inflating the
5 balloon to anchor the proximal end of the endoluminal device against the body lumen.

1 39. The method of claim 37 further comprising a proximally retractable
2 retrograde sheath mounted concentrically over the shaft and inner sheath and extending
3 axially over the proximal end of the endoluminal device and the balloon, the method further
4 comprising inflating the balloon to anchor the proximal end of the endoluminal device against
5 the retrograde sheath and then retracting the retrograde sheath after deflating the balloon.

1 40. The method of claim 36, wherein the anchoring means comprises a
2 tether releasably attached to the proximal end of the endoluminal device, the method
3 comprising separating the tether from the endoluminal device prior to step (d).

1 41. The method of claim 40, wherein the introducer further comprises a
2 proximally retractable retrograde sheath mounted concentrically over the shaft and inner
3 sheath; a medial sheath mounted concentrically between the inner sheath and the retrograde
4 sheath in the retrograde portion of the introducer and terminating proximally of the proximal
5 end of the endoluminal device; and the anchoring means comprises a tether releasably
6 attached to the proximal end of the endoluminal device and non-releasably attached to a distal
7 end of the retrograde sheath, the method comprising retracting the retrograde sheath to
8 separate the tether from the endoluminal device prior to step (d).

1 42. The method of claim 41, wherein a portion of the retrograde sheath
2 extends over a portion of the endoluminal device, the method comprising retracting the
3 portion of the retrograde sheath extending over the endoluminal device prior to step (c).

1 43. The method of claim 40, wherein the introducer further comprises a
2 proximally retractable retrograde sheath mounted concentrically over the shaft and inner
3 sheath and the anchoring means comprises a tether releasably attached to the proximal end of

the endoluminal device and non-releasably attached the inner sheath, the method comprising separating the tether from the endoluminal device during retraction of the introducer in step (d).

44. The method of claim 36, wherein the introducer further comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath; a medial sheath mounted concentrically between the inner sheath and the retrograde sheath in the retrograde portion of the introducer and terminating proximally of the proximal end of the endoluminal device; and the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the medial sheath and the retrograde sheath, the method further comprising releasably confining the extended portion between the retrograde sheath and the medial sheath until after step (c), and then retracting the retrograde sheath relative to the medial sheath a distance sufficient to release the extended portion from the notch.

45. The method of claim 44, wherein the retrograde sheath extends over a retrograde portion of the endoluminal device, the method comprising retracting the portion of the retrograde sheath extending over the endoluminal device prior to step (c).

46. The method of claim 36, wherein the introducer further comprises a proximally retractable retrograde sheath mounted concentrically over the shaft and inner sheath and the anchoring means comprises a proximally extended portion of the endoluminal device and a notch in one or both of the inner sheath and the retrograde sheath, the method further comprising releasably confining the extended portion between the retrograde sheath and the inner sheath until after step (c), and then retracting the retrograde sheath relative to the inner sheath sufficient to release the extended portion from the notch.

47. An introducer for deployment of an endoluminal device in a distal location from a proximal location, the introducer comprising:

a retrograde portion;

an anterograde portion, axially movable relative to the retrograde portion, comprising a distal tip and an anterograde sheath attached proximally to the distal tip;

6 a shaft attached to the distal tip and extending concentrically through a central
7 lumen defined by the anterograde portion and retrograde portion;

8 an endoluminal device mounted concentrically over the shaft in the central
9 lumen and having a distal end contained by the anterograde portion and a proximal end
10 contained by the retrograde portion; and

11 an inflatable balloon mounted radially inside the retrograde portion for
12 anchoring the endoluminal device during deployment of the device from the device proximal
13 end to the device distal end.

1 48. The introducer of claim 47 further comprising an inner sheath mounted
2 concentrically over the shaft underneath the endoluminal device, the inner sheath defining a
3 lumen connected to an inner region of the inflatable balloon for communication of a fluid to
4 the balloon for inflation of the balloon, wherein the retrograde portion comprises a
5 proximally retractable retrograde sheath mounted concentrically over the shaft and the inner
6 sheath and extending distally over the balloon and a retrograde portion of the endoluminal
7 device.

1 49. A method for deployment of an endoluminal device in a distal location
2 in a body lumen from a proximal location, the method comprising the steps of:

3 (a) inserting an introducer into the body lumen having a lumen wall, the
4 introducer comprising a retrograde portion, an anterograde portion comprising a distal tip
5 and an anterograde sheath attached proximally to the distal tip, a shaft attached to the distal
6 tip and extending concentrically through a central lumen defined by the anterograde portion
7 and retrograde portion, an endoluminal device mounted concentrically over the shaft in the
8 central lumen and having a distal end contained by the anterograde portion and a proximal
9 end contained by the retrograde portion, an inflatable balloon mounted inside the retrograde
10 portion for anchoring the endoluminal device during deployment of the device, and a
11 proximally retractable retrograde sheath extending distally over the balloon and the proximal
12 end of the endoluminal device;

13 (b) aligning the proximal end of the endoluminal device in a deployment
14 location;

15 (c) retracting the retrograde sheath to allow a proximal portion of the
16 endoluminal device including the proximal end to deploy;

(d) inflating the balloon to compress the proximal portion of the endoluminal device against the lumen wall; and

(e) extending the shaft to distally advance the anterograde sheath to deploy a remaining portion of the endoluminal device.

1 50. The introducer of claim 5, wherein the anchoring means further
2 comprises a holder in the anterograde portion concentrically mounted to the inner sheath and
3 adapted to prevent distal movement of the endoluminal device during distal advancement of
4 the anterograde shaft.